

Application No. 10/589862
Response to the Office Action dated July 8, 2010

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REMARKS

Favorable reconsideration of this application is requested in view of the above amendments and following remarks.

Claims 1 and 11 have been amended editorially and as further supported by example 1 on page 5 of the specification.

Claims 1-8, 11-15, and 18 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Deshpande et al. (U.S. Patent Application Publication No. 2004/0028737) in view of Mehra et al. (U.S. Patent No. 5,733,575). Applicants respectfully traverse this rejection.

Claim 1 is directed to a non-toxic, edible, enteric film coating, dry powder composition for use in preparing an aqueous enteric coating suspension for coating of substrates, and claim 1 recites the dry powder composition including methacrylate copolymer of Type C of about 20-90 wt%, a plasticizer, a film coating detackifier, and an opacifier and that the dry powder composition does not contain any alkalinizing agent. The specification describes that the alkalinizing agent neutralizes free carboxylic acid and forms a salt thereof (see page 3, lines 1-6).

Deshpande discloses use of 2M ammonia solution to adjust pH to neutrality 7-7.5 when methacrylate copolymer of Type C is included (see abstract and examples 1-4 in paras. [0045] and [0049] on page 3 and [0053] and [0057] on page 4), and the reference fails to disclose that the enteric coating composition does not include an alkalinizing agent when the methacrylate copolymer of Type C is included in an amount of about 20-90 wt% in the enteric coating dry powder composition as claim 1 recites (see *id.*). The alkalinizing agent is explained in the specification by referring to Lehmann et al. (U.S. Patent No. 4,520,172) and Chittamuru et al. (U.S. Patent No. 6,420,473), both of which are incorporated by reference into the specification (see page 2, lines 7-15 of the specification). Lehmann discloses ammonia as a particularly effective alkali and further discloses that an ammonia solution is added to emulsion polymer of methacrylic acid and ethyl acrylate (see coln. 4, lines 52-65 and example 3 in colns. 6-7). Chittamuru lists

Application No. 10/589862
Response to the Office Action dated July 8, 2010

ammonium compounds such as ammonium carbonate and ammonium bicarbonate, which provides an ammonium ion when dissolved in an aqueous solution, as an alkalinizing agent of a carboxylic acid group in an acrylic resin (see abstract and coln. 4, lines 6-34). Thus, the specification of the present application clearly indicates the ammonia solution as the alkalinizing agent. The alkalinizing agent stabilizes the coating resin by neutralizing free carboxylic acid groups, which destabilize the coating resin (see page 2, lines 26-31 of the specification). Generally, when the free carboxylic acid groups are not neutralized, the composition is not stable, and the coating would not be resistant to stomach environment (see page 3, lines 1-9 of the specification). In contrast, without using the alkalinizing solution, the dry powder composition of claim 1 can be stable and stored for long time, have no caking or no agglomeration, and provide the coating with good tensile strength without tack (see page 2, line 18 - page 3, line 9). Also, without using the alkalinizing agent, i.e., without neutralizing the composition, the enteric coating provided with the dry composition of claim 1 would not include a salt formed from the ammonium agent and free acid(s) (see *id.*). Moreover, because the neutralizing step with the alkalinizing agent is not necessary, concentrations of the components in the dry powder composition of claim 1 do not vary by adding the alkalinizing agent, which may vary or might be added in an excess amount and exist in the coating suspension as a free alkali. By eliminating the alkalinizing agent from the composition, the enteric coating using the composition of claim 1 would not only reduce the handling time during coating the substrates, particularly in industrial scale manufacturing, but also ensure the uniform quality of the coating suspension such as uniform concentrations of the components in the coating composition, no salt formed with the alkalinizing agent, and no free alkali in the suspension as discussed above. The reference, which uses the alkalinizing agent, cannot enjoy these advantages. Accordingly, claim 1 is distinguished from Deshpande.

Mehra, which discloses inclusion of an alkalinizing agent in an enteric film coating dry powder composition (see coln. 2, lines 33-52), does not remedy the deficiencies of Deshpande. Thus, claim 1 and its dependent claims 2-8, 12-15, and 18 are distinguished from Deshpande in view of Mehra.

Claim 11 is directed to a process of making a dry powder enteric film coating composition and recites the composition that does not contain any alkalinizing agent

Application No. 10/589862
Response to the Office Action dated July 8, 2010

similar to claim 1. Thus, claim 11 is distinguished from Deshpande in view of Mehra for at least the same reasons as discussed for claim 1 above.

Accordingly, this rejection should be withdrawn.

Claims 9-10 and 16-17 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Deshpande et al. (U.S. Patent Application Publication No. 2004/0028737) in view of Mehra et al. (U.S. Patent No. 5,733,575) and Kokubo et al. (U.S. Patent No. 4,948,622). Applicants respectfully traverse this rejection.

Claims 9-10 and 16, which ultimately depend from claim 1, and claim 17, which depends from claim 11, are distinguished from Deshpande in view of Mehra for at least the same reasons as discussed for claim 1 and claim 11 above, respectively.

Kokubo does not remedy the deficiencies of Deshpande in view of Mehra. Accordingly, this rejection should be withdrawn.

In view of the above, Applicants request reconsideration of the application in the form of a Notice of Allowance.

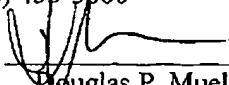


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DPM/my/jes

Respectfully submitted,

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